RECORD OF ORAL HEARING

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte SOLOMON S. STEINER, ROBERT FELDSTEIN,
PER B. FOG and TRENT POOLE

Appeal 2007-0742
Application 09/621,092
Technology Center 3700

Oral Hearing Held: April 26, 2007

Before ROBERT NAPPI, ANITA GROSS, and LINDA HORNER
Administrative Patent Judges

ON BEHALF OF THE APPELLANT:

RIVKA D. MONHEIT, ESQUIRE
Pabst Patent Group, LLP
400 Colony Square, Suite 1200
1201 Peachtree Street
Atlanta, GA 30361

ALSO PRESENT:

DR. DAVID DIAMOND

The above-entitled matter came on to be heard on April 26, 2007, commencing at approximately 9:18 a.m., at the United States Patent and Trademark Office, 600 Dulany Street, Alexandria, Virginia, before Leanne M. Krivonak, Notary Public.

JUDGE GROSS: Whenever you're ready, it's ten minutes by that clock.

MS. MONHEIT: My name is Rivka Monheit and I'm here on Appeal Number 2007-0742, which is regarding Application Number 09/621092.

Also, I want to take the time to introduce Dr. David Diamond of the ManKind Corporation. He's a senior director of intellectual properties and he also has demonstration of the capsule and the inhaler that we can point to later on.

As you know in this case, we have a few claims pending. Claims 28 to 30 and 41 and 43 and 45 are pending. The examiner indicated that claims 28 and 29 were merely rejected to -- depending on from rejected claims. So those are not on appeal.

The claims on appeal are claims 30, 41, 43 and 45. And claim 41 is the sole independent claim, and so we'll start with that independent claim.

JUDGE HORNER: What about 44; do you have that?

MS. MONHEIT: 43 to 45.

JUDGE HORNER: Oh, 43 to 45. Okay. I misunderstood. Thank you.

MS. MONHEIT: These claims define capsules the container use in an inhaler and inhalers are used to deliver medicament to pulmonary inhalation.

As I mentioned, Dr. Diamond brought with him today an example of

both an inhaler and inside of the inhaler is the capsule. I'm just letting you know this is actually an actual product that is being protected by this patent and related to this application and related application.

And it's currently undergoing phase 3 clinical trials. So this is something that is very important to our client, and you can have a very smaller presentation of the capsule.

And so what we'll be talking about a little bit more -- if you guys want to, I can hand it to you or we can leave it on the table, but they are keying surfaces at the different ends, and if you would like to, we can pass it around.

JUDGE HORNER: We would like to --

MS. MONHEIT: Sure. I'm going to pass it with the device. And actually, David, if you want to just demonstrate putting it in and closing it, then we can talk a little bit more about that later.

MR. DIAMOND: It has -- I don't know what the name of the shape is on the bottom. There is a shape on the bottom and there is also a notch up at the top and it mates with a similar shape at the bottom and a slot here at the top so that there is only -- if you put it in the wrong rotational orientation, it can't go all the way in.

But if you put it -- if you align the keying surfaces, it goes all the way in.

JUDGE HORNER: Okay. Thank you.

JUDGE GROSS: Thank you.

MS. MONHEIT: Take it out and put it in, get a feel for -- so this is one embodiment about what the claims are covered. And in this case again the claim we're focusing on the capsule, there are other applications that are

directed to the inhaler itself.

As you can see, as you pass it around, there's a keying surface at the top and actually at the bottom as well.

In this particular embodiment, the capsule has keying surfaces at both ends and one that ensures the capsule is oriented properly and allows the device to function properly, and one at the top that can also help people identify medicaments and assist the patient in selecting the correct drug.

So we see this also described more generally in claim 41, which I'll just run through briefly. It defines a capsule to contain drug for use inhaler, comprising at least one keying surface on an outside surface of a distal end of a capsule, is adapted it [sic] to orient the capsule within the inhaler or identify the drug to be placed in the capsule and at least one hole allowing air to pass in through and out of the capsule.

Now, there's really only one reference that has been cited. We have a section 102 rejection over the Keritsis patent, which is U.S. Patent Number 4991605. And we'll start with the independent claim and some points of difference between the independent claim and the embodiment both in Keritsis.

Keritsis describes a container for added material for smoking articles. This container is adding -- is designed to contain flavorants to make smoking more pleasurable to the user.

The examiner really focused on one embodiment -- we can talk about others as well -- but the one that the examiner focused on in her rejection was figure 6, 6-A and 7, which is described in column 5, beginning around line 51.

There Keritsis explains that the element 610, 620 and 630 combined

to form a container which can then be used to contain the additive material. So the container is described in 600 and it's illustrated in figure 6, 7 and 6-A.

What we can see is that a container even as described as in Keritsis is not half a tube or an open tube. It's something that can be used to contain this material such as in case is a flavorant and our case a drug or an medicament.

The examiner even cited the definition, because we seem to have some discrepancy about what a container was, what a capsule was, and he cited to Webster's 10th addition, and even the definition that he cites further substantiates this view.

One of the definitions he uses is a compact, often sealed and detachable container or compartment that comports completely with the way we were using -- we're using word in the specification such as the way we've described capsules on pages 9 to about page 12 of the application.

We described something as attachable as you can see in this example, that put into a device that you can take out of the device and it's designed to contain material inside of it.

JUDGE HORNER: What about the examiner in the answer -- I think in response, partly in response to the issue of the container or capsule being a closed vessel -- points to column 6 of the prior-art reference, lines -- it looks like 7 and 8 where it describes an alternate embodiment of the element 610 that describes the open end could be closed.

MS. MONHEIT: Yes, I found that to be interesting as well because I think both the examiner and I have overlooked that one little sentence, because most of the embodiments -- and I did go through every one -- looked at every element -- actually are describing something as the -- as

even Keritsis states that it requires putting all -- either two or three different pieces, different elements -- together to create a container.

I'm not sure exactly what they mean by the phrase, Alternatively, the open end of the element 610 could be closed.

There is an example just below that where they talk about how usually when they talk about how element 630, 620 and 610 combine, they describe 630 attaching to the inner surface of 620, and if you go down a little bit, they talk about in -- I believe it is line 32, they say, Well, element 630 could be the cap on 610. It could combine there.

JUDGE HORNER: Yes.

MS. MONHEIT: So one interpretation could mean that -- what they mean closed is that it could be closed by 630.

JUDGE HORNER: And why wouldn't that be a capsule -- the combination of 610 and 630 form the capsule just like you have two pieces that combine together to form your capsule?

MS. MONHEIT: Right. Because it forms a container with the top and the bottom and you can put something inside it and it will be closed at both ends. So that would be one reading of this.

Unfortunately, they don't really expand on it, and really every embodiment that they describe and is depicted in their pictures has 620 or a similar-type element that's opened at one end and closed at the other.

And they combine -- and really what's going on -- I mean, they're trying to mass produce this in a cheap manner, being attached to a cigarette or something, and probably sold with that article is the way that I'm understanding it, very small, kind of cheap thing.

So whatever you can do to make it cheap, fast, efficient to put this

together would be the way -- probably the way they would choose to manufacture it.

Theoretically reading it at face value, it could mean that 610 is closed at one end and at the other. And even if we took that interpretation, you are still missing a key element, which is having the keying surface on an outside surface of the distal end of the capsule. And we can move over to keying surface at this point.

What the examiner points to as an example of a keying surface is element 613. Element 613 is an actually grooved outer surface that extends upon the entire length of element 610.

Something which extends along the entire length is not something that you would normally use the words at this distal end. And you can even see that in Keritsis itself. It talks about -- the way it describes things, it talks about various elements such as element 610 that extends along the entire length -- and let me see if I can find it.

But when you want to say where something is located in a device claim and you want to see if it has a specific point and it's at an end, you'll say the distal end or the proximal end. Those are -- that's the common language that's used in this art to describe a location of an element.

So I think it's a bit of a strained reading to take something that runs along the entire length of a tube and say, Oh, that's the same as saying that there is a keying surface at a distal end of a particular capsule.

JUDGE HORNER: I think where we may have a little confusion is in claim 41, it says that at least one keying surface on an outside surface of a distal end.

MS. MONHEIT: Yes.

JUDGE HORNER: So it's saying the keying surface is not on the distal end, but on the outside surface of the distal end and so could it -- for example, in figure 7 of the prior art, couldn't the -- if we take the face -- the end face of 610 --

MS. MONHEIT: I think that's supposed to be -- actually, that's supposed to be 616. It's just not very --

JUDGE HORNER: Okay. So let's say that's the distal end. So couldn't the outside surface be the perimeter of that which shows an undulating pattern that's a keying surface? Because you're claiming it's on the outside surface of the distal end.

MS. MONHEIT: I think it's a possible reading. I don't think that was intended by what Keritsis was describing.

I think there is another -- I'm sorry.

(Pause in the proceedings.)

MS. MONHEIT: Right, right. That's what we're talking about -- is that on the inside of the capsule or outside the capsule. It's outside, it's not inside. So the outside surface of the distal end indicates where it is in respect to the capsule itself.

Something else that we can point to as well is the difference that again, even if we want to take 610 as having a closed end at each end, it's not designed -- it's not designed to produce an inhaler.

And you can see the way applicants use the word inhaler is again the way it would commonly be used in the medical device arts, that as a device that stands alone that is used to deliver a medicament.

We describe it -- for example, we describe various types of inhalers in the background of the invention and also through the application. We also

have a description of a particular inhaler which is related to the one that's before you.

These art devices -- they are designed to deliver the medicament to be an inhalation to the pulmonary region of a patient.

I don't know what in the figure 7 or 6 or 6-A the examiner was trying to say that, okay, maybe the combination of element 620 with 630, you could somehow characterize as an inhaler.

Again, I think that's a very -- a very twisted reading of what's going on here. This is designed to be used -- to contain an additive. It's designed to be attached to a smoking article. The smoking article is lit and it's -- the combustion is being used to mix the gases together and volatilize the additive and then deliver that to the user.

There's nothing here that shows 620 plus 630 as somehow being as only a stand-alone device to be designed somehow to deliver a capsule containing a medicament to the end-user.

So even trying to kind of manipulate what's described here to fit somehow what the examiner was arguing, I think it was a very twisted reading of what is defined here.

Does that answer your question?

JUDGE HORNER: Well, let's talk a little bit about the medicament because I noticed in the prior art that it describes some of the additives and one of them that sort of popped out to me was menthol because that is used an additive or flavorant in cigarettes, but it's also used in cough drops; it's used to soothe sore throats. Why wouldn't that be a medicament?

MS. MONHEIT: Again, I'm not sure exactly what they're doing here aside from what they say they're doing, which is, if you look in column 8,

from anywhere from line 1 all the way down line 33, they're very clear about what their purpose here is.

This is a flavorant. This is something that's being used to enhance the flavor -- I'm actually -- I was never a smoker and so I'm not sure exactly what it tastes like to smoke a cigarette and what it's like to enhance the flavor of a cigarette.

But for whatever reason, this is something that people might be desirous of and they think that this will make it taste better to people.

They talk about various elements that can be there, but these are not used to cure anyone, these are not used to heal someone, I mean, which is the essential concept of what a medicament is.

JUDGE HORNER: Well, let me try --

MS. MONHEIT: So when --

JUDGE HORNER: -- it's intended to, but --

MS. MONHEIT: And the byproduct of menthol -- I don't even know in this particular -- the way that it's being delivered that it would have that effect. It doesn't appear to be capable of that.

I mean, you've got tar going to the lungs and everything. I don't think it's having a healing -- it doesn't appear to be having a healing effect.

They don't give enough information to describe that that is having a healing effect, and clearly that's not -- the focus is on adding the right amount so that it tastes good, not adding the right amount so that you don't have a cough or adding the right amount so that we undo somehow this carcinogen that's being supplied to the lungs.

It's really -- again, we would be reading a lot into here and adding a lot to make this somehow a medicament. That's just not the amount we're

talking about, it's not the ratios we're talking about, it's not at all the focus of this --

JUDGE NAPPI: I'm hearing you use a lot of words that aren't in the claim. I'm hearing you use the words -- the claim says a capsule for a drug.

You're talking for use of an inhaler, you're talking about medicaments, you're talking about treating pulmonary things, you're talking about the keying surface not being along the whole length, only being on the distal end.

MS. MONHEIT: Yes

JUDGE NAPPI: I don't see "only on the distal end" in the claim. I don't see "medicament" in the claim.

MS. MONHEIT: Okay. Well, let's --

JUDGE NAPPI: Can you --

MS. MONHEIT: Sure.

JUDGE NAPPI: You know, I understand that your invention as disclosed and the inventions disclosed in the prior art are --

MS. MONHEIT: Yes.

JUDGE NAPPI: -- very different devices.

MS. MONHEIT: Thank you.

JUDGE NAPPI: I got that.

MS. MONHEIT: I appreciate that.

JUDGE NAPPI: I think the examiner got that. You have some claims that are objected to, correct?

MS. MONHEIT: Yes.

JUDGE NAPPI: Okay. Can we, you know --

MS. MONHEIT: Well, just to take one step back, I believe that you --

I had started at claim 41, but we had jumped to a few different claims in our discussion.

JUDGE NAPPI: Okay.

MS. MONHEIT: So to address the first question you asked about, medicament, that's the specific -- on specific claim 30 where it says that medicament is in the capsule. So just to clarify that, and I didn't make that clear in my response to her question.

To get back to your question about the keying surface in this location, I believe that claim 41 does set forth exactly the location of at least one keying surface that we say must be there.

It says again that it's on an outside end of a distal end of the capsule. That phrase, "distal end of the capsule," is telling you the location of the keying surface.

JUDGE NAPPI: But it doesn't mean it can't be across the whole capsule. You said it --

MS. MONHEIT: I believe that --

JUDGE NAPPI: -- that doesn't include something running the whole length of the capsule.

MS. MONHEIT: I --

JUDGE NAPPI: How I read that is as long as on the distal end, if it's on the whole thing, and the distal end, your claim doesn't preclude that because it doesn't say --

MS. MONHEIT: That would not --

JUDGE NAPPI: -- only a distal end.

MS. MONHEIT: Based on my experience in reading claims and reading the art in the way that you describe a medical device, that would not

be the way that someone would describe the location of a keying surface if they wanted it to include the keying surface along the length.

Again, I believe it's not a clear reading of claim 41 on its face, and if for some reason there was some confusion and we looked to a specification to try to see what do we mean by "distal end," it's very clear throughout the specification.

If we start on page 9, which is where did define the capsule, and if we look at some of the illustrations, some of the drawings that go along with it, when we talk about ends, we're talking about a specific location of the capsule.

We're not talking about something that's at that location and throughout the entire capsule. That's just not the way we're speaking. It's not the way that this specification was drafted and that's the not the way I'm familiar with drafting medical device claims.

JUDGE HORNER: I looked for "distal end" in the specification and I didn't see it. What I saw was the description of the keying surface being on the closed end.

MS. MONHEIT: Closed end, yes.

JUDGE HORNER: So this "outside surface of a distal end" language is different from anything described in the specification. And so our mandate is to give it the broadest reasonable interpretation, and in view of the specification, while not reading a specific embodiment from the spec into the claims.

And so since that terminology wasn't used in the specification, we're looking at this pretty broadly and saying, what does "outside surface of a distal end" mean and what does "distal" mean? Distal to what?

You know, I'm used to seeing "distal end" in terms of, for example, describing a catheter that's placed into a body, and you've got proximal and distal. But here it's a capsule with two ends. But what's distal to what?

MS. MONHEIT: And actually, if you look at the file history, the immediate language that was used immediately prior to the claims on appeal had been "closed end." It was replaced with "distal end," presumably thinking that it was more specific, that it was at the end -- really at the end.

That, I believe, was the intention of the use of the term "distal" as -- instead of "closed end." But the intention was to describe the location more specifically as to be specific as to where the keying surface is located.

And I -- as I'm sure you've seen, people use the term "proximal" and "distal" to describe a location, even if that specific word is not used in the application, because it's just a common way of describing that area that we are talking about in the application.

Getting back to your other question about -- we talked about keying surfaces, distal end. I also want to go through a few of the dependent claims.

We talked briefly about claim 30. I just want to also point out that if we get to, for example, claim 44, we have nothing in Keritsis that describes, identifying the drug to be placed in the capsule, let alone the additive to be placed in the capsule.

The examiner had focused on that it couldn't -- that the capsule -- that the container could be configured and that it could be -- that its dimensions could be modified to accommodate different smoking articles.

So if it's a large smoking article or smaller smoking article, well, that's the smoking article that it could be attached to. It's not describing what's

inside the container.

There seems to be -- so that was particularly where the examiner was talking about -- for example, he had cited to column 7, the first paragraph in column 7, and again, what they're talking about there is that we could have different dimensions for this container.

It could be a little bit larger, it could be a little bit smaller, and that would be used to define which smoking article it could be attached to; again, not to identify what kind of additive is on the inside alone what kind of medicament, if there was a medicament on the inside.

So I don't think there is anything with respect to claim 44 present and current.

In addition, with respect to claim 45 where we specified that both keying -- that there are two keying surfaces present, one which is adapted to orient it within an inhaler and another which is identified through drugs we placed in the capsule -- again, they don't -- I don't think they describe either -- or even like we just described with respect to claim 44, the culmination of having both, one at each end, is -- I don't think there is anything Keritsis -- that describes that as well.

JUDGE HORNER: So your definition of inhaler was a device that stands alone?

MS. MONHEIT: Yes.

JUDGE HORNER: That's used to deliver a medicament.

MS. MONHEIT: Yes, and you'll see if we just take -- you just flip through the application, we say what's the present field of the invention, the field of inhalers. We use this term thinking we're talking about medical devices.

This is very much -- we sometimes talk about inhaler devices. We sometimes talk about dry powder inhalers, we sometimes talk about medicinal inhalers, different types of inhalants.

But all of these are with the understanding that when the medical field is talking about delivering medicaments to a person -- to a patient -- and that what you can do is you can -- you have the inhaler such as the one before you where it's a stand-alone device and you insert a capsule into it and that is removable, detachable from and stands alone also on its own and can be placed inside the orbit -- and then deliver the drug to the user who can use their own.

So I think -- yeah, I think the preamble of this case can be viewed as adding -- as having a structural way of modifying the capsule and helping to define what kind of a capsule we're talking about here.

JUDGE GROSS: Is that everything?

MS. MONHEIT: Yes.

JUDGE GROSS: Do you have any more questions?

(No response.)

JUDGE GROSS: Thank you. I think we have the issues.

Whereupon, the proceedings at 9:39 a.m. were concluded.